

Package Leaflet: Information for the user

Latanoprost / Timolol 50 micrograms/ ml + 5 mg/ ml Eye Drops, Solution

(Latanoprost + Timolol)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Latanoprost / Timolol 50 micrograms/ ml + 5mg/ ml Eye Drops, Solution is referred to as 'these eye drops' in this leaflet.

What is in this leaflet

1. What these eye drops are and what they are used for
2. What you need to know before you use these eye drops
3. How to use these eye drops
4. Possible side effects
5. How to store these eye drops
6. Contents of the pack and other information

1. What these eye drops are and what they are used for

These eye drops contain two active ingredients: latanoprost and timolol.

Latanoprost belongs to a group of medicines known as prostaglandin analogues. It increases the natural outflow of fluid from the eye into the bloodstream.

Timolol belongs to a group of medicines known as beta-blockers. It slows down the production of the fluid in the eye.

These eye drops are used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you these eye drops when other medicines have not worked adequately.

2. What you need to know before you use these eye drops

These eye drops can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use these eye drops

- if you are allergic (hypersensitive) to Latanoprost or Timolol, beta- blockers or any of the other ingredients of these eye drops (listed in section 6)
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have serious heart problems or heart rhythm disorders.
- if you are pregnant (or trying to become pregnant)
- if you are breast feeding

Warnings and precaution

Talk to your doctor or pharmacist before using these eye drops if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heartbeat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes, as timolol may mask signs and symptoms of low blood sugar
- over activity of the thyroid gland as timolol may mask signs and symptoms
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past.
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use these eye drops but follow the instructions for contact lens wearers in Section 3
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Tell your doctor before you have an operation that you are using these eye drops as timolol may change effects of some medicines used during anaesthesia.

Other medicines and these eye drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.

These eye drops can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicines or medicines to treat diabetes.

In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Beta-blockers
- Epinephrine
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrhythmics, digitalis glycosides or parasympathomimetics
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine

These eye drops with food and drink

Normal meals, food or drink have no effects on when or how you should use these eye drops.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not use these eye drops if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or planning to become pregnant.

Breast-feeding

Do not use these eye drops if you are breast-feeding. These eye drops may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Fertility

Latanoprost and timolol have been found no effect on male or female fertility in animal studies.

Driving and using machines

When you use these eye drops your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

These eye drops contains benzalkonium chloride and phosphate buffers

These eye drops contains 0.2mg/ml (0.006mg per drop)benzalkonium chloride as preservative. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the

contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. See the instructions for contact lens wearers in section 3.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor. These eye drops contains 6.3 mg phosphates in each milliliter which is equivalent to 0.2 mg per drop.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. HOW TO USE THESE EYE DROPS

Always use these eye drops exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults (including the elderly) is one drop once a day in each affected eye(s).

Do not use these eye drops more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use these eye drops as instructed by your doctor until your doctor tells you to stop.

Your doctor may want you to have extra checks on your heart and circulation if you use these eye drops.

Contact lens wearers

If you have contact lenses, do not use these eye drops while your contact lenses are in your eyes, remove your contact lenses before using these eye drops, wait at least 15 minutes after using these eye drops before putting your contact lenses back in.

Instructions for use:

1. First wash your hands and sit or stand comfortably
2. Remove your contact lenses
3. If you are using the bottle for the first time, snap off the protective cover by turning it clockwise to break the seal.
4. Unscrew the cap
5. Tilt your head back and look at the ceiling
6. Pull the lower eyelid gently downwards
7. Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
8. Avoid touching the eye (or any other surface) with the tip of the bottle



9. Close the affected eye. Press your fingertip against the inside corner of the closed eye by the nose, and hold for 2 minutes. This is important because it reduces the amount of latanoprost and timolol getting into the rest of your body.



10. Repeat for the other eye if your doctor has told you to do this.
11. Put the cap back on the bottle and tighten onto the nozzle after every use.

If you use these eyedrops with other eye drops

Wait at least 5 minutes between using these eye drops and using other eye drops.

If you use these eye drops more than you should

If you put too many drops in your eye you may experience some minor irritation in your eye and they may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow these eye drops

If you accidentally swallow these eye drops you should contact your doctor for advice. If you swallow a lot of these eye drops you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use these eye drops

Carry on with your next dose at the usual time.

Do not use a double dose to make up for a forgotten dose.

If you are unsure about anything talk to your doctor or pharmacist.

If you stop using these eye drops

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these eye drops can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using these eye drops without speaking to your doctor.

Listed below are known side effects of these eye drops. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that these eye drops might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using these eye drops.

The following are the known side effects of using this eye drops:

Very common- (may affect more than 1 in 10 people)

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use these eye drops in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after these eye drops are stopped.

Common- (may affect up to 1 in 10 people)

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon- (may affect up to 1 in 100 people)

- Headache.
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, swelling (inflammation) of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)

Other side effects

Although not seen with these eye drops, the following additional side effects have been seen with Latanoprost and Timolol, which are in these eye drops. They might occur when you use these eye drops.

The following side effects have been seen with latanoprost:

Infections and Infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Immune System Disorders:

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Psychiatric Disorders:

- Depression, memory loss, decreased sex drive, inability to sleep, nightmares.

Nervous System Disorders:

- Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope).

Eye Disorders:

- Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye. swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dryeyes, fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).

Ear Disorders:

- Whistling/ringing in the ears (tinnitus).

Heart (Cardiac) Disorders:

- Angina, Worsening of angina, awareness of heart rhythm (palpitations).

Breathing (Respiratory) Disorders:

- Asthma, worsening of asthma, shortness of breath.

Skin Disorders:

- Darkening of the skin around the eyes.

Muscle and Skeletal Disorders:

- Joint pain, muscle pain

General Disorders:

- Chest pain

Like other medicines applied into the eyes, these eye drops are absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with intravenous and/ or oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels
- Depression, memory loss, difficulty sleeping (insomnia), nightmares, hallucinations.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles and headache

- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Slow heart rate, chest pains, awareness of heart beat (palpitations), oedema (fluid buildup), changes in rhythm or speed of the heartbeat and congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid buildup), a type of heart rhythm disorder, heart attack, heart failure
- Low blood pressure, Raynaud's phenomenon and cold hands and feet
- Difficulty breathing, cough, constriction of the airways in the lungs (predominantly in patients with pre-existing disease)
- Feeling sick (nausea), diarrhoea, dry mouth, taste disturbances, indigestion, abdominal pain, vomiting
- hair loss/baldness, skin rash, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- Muscle pain not caused by exercise
- Muscle weakness/ tiredness
- Sexual dysfunction, decreased libido

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store these eye drops

Keep this medicine out of the sight and reach of children.

Do not use these eye drops after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Store the unopened bottle of eye drops in a refrigerator (between 2°C and 8°C).

After opening the bottle it is not necessary to store it in a refrigerator but do not store it above 25°C.

After opening do not use the eye drops in this bottle for more than 4 weeks.

When you are not using these eye drops, keep the bottle in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What these eye drops contain

The active substances are latanoprost and timolol

Each ml contains 50 micrograms latanoprost and 5 mg timolol (as 6.8 mg timolol maleate)

The other ingredients (excipients) are:

Sodium chloride, Benzalkonium chloride, Sodium dihydrogen phosphate monohydrate, Disodium phosphate anhydrous, Hydrochloric acid solution and Sodium hydroxide solution (for pH adjustment), Water for injections.

What these eye drops look like and contents of the pack

Each carton contains one bottle of these eye drops. Each bottle contains 2.5 ml of these eye drops.

These eye drops are clear and colourless liquid.

These eye drops are available in pack sizes of 1, 3 and 6. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

FDC Pharma

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